REMARKS

Applicant notes that this response is being filed within two months of the mailing of a Final Office Action. The remarks are intended to put the application in condition for allowance, or to at least reduce the issues upon appeal, and therefore, entry to the record is respectfully requested. Applicant respectfully requests reconsideration of the present application in view of the reasons that follow.

Claims 1, 2, 4-25 and 43 are pending in this application. No claims are amended.

I. Claim Rejections Under 35 U.S.C. § 102.

Claims 1, 2, 4-12, 16-25, and 43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,241,730, issued to Alby. Applicant respectfully traverses this rejection.

Contrary to the Examiner's assertion in the Final Office Action, Alby clearly does not teach each and every element of the presently claimed invention. In particular, Alby does not teach a disc prosthesis, or disc nucleus replacement. Claim 1 of the presently claimed invention recites:

> A spinal stabilization system comprising:
>
> (a) a stabilizing element comprising a first segment and a second segment, the first and second segments connected by a pivoting joint;
>
> (b) a first connector adapted to connect the stabilizing element to a first vertebra in a spinal column;
>
> (c) a second connector adapted to connect the stabilizing element to a second vertebra in the spinal column; and
>
> (d) a disc prosthesis or a disc nucleus replacement adapted to be disposed between two adjacent vertebrae in the spinal column.

Hence, a system is presented having a stabilizing element AND a disc prosthesis or disc nucleus replacement. The system allows for the maintenance of motion between the affected vertebrae so that motion is preserved, as described by the specification. The claim clearly states both elements, and both elements must be given weight in determining the patentability of the claim in view of Alby.

A disc prosthesis is fully described by the present specification in paragraph 6:

> ...disc prostheses may be inserted in place of a natural vertebral disc in order to simulate at least some of the natural intervertebral movement and to restore proper disc height. Ideally, a disc prosthesis will operate in conjunction with the facet joints to restore the full range of motion of the spine.

This is not mere exemplification, but is a description of a disc replacement, where it is "inserted in place of a natural vertebral disc." Furthermore, a disc nucleus replacement is exactly as described, in that it replaces a disc nucleus. Such items are more fully described with reference to at least figure 7 of the specification as originally filed. In figure 7, a disc prosthesis 724, is shown sandwiched between adjacent vertebrae. To "replace" a disc nucleus requires that the item be placed where the disc nucleus would naturally reside. To use anything outside of the alignment within the spinal column would not be a disc prosthesis or disc nucleus *replacement*.

The description and figures in the specification are more than mere exemplification of these claim elements. The specification provides clear guidance to one of skill in the art to understand what is meant by the terms disc prosthesis and disc nucleus replacement. As stated by the Federal Circuit in *Phillips*:

> The claims, of course, do not stand alone. Rather, they are part of "a fully integrated written instrument," consisting principally of a specification that concludes with the claims. For that reason, claims "must be read in view of the specification, of which they are a part." As we stated in Vitronics, the specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; *it is the single best guide* to the meaning of a disputed term."

Phillips v. AWH Corp., 415 F.3d 1303, 1323 [75 USPQ2d 1321, 1328] (Fed. Cir. 2005) (en banc) (citations omitted, emphasis added). The description of the terms in the specification should be the single best guide to the interpretation of the claim elements. Here, even the words of the claims themselves (i.e. "disc prosthesis" – a prosthetic disc; and "disc nucleus replacement" – replaces a disc nucleus) are dispositive. The terms fully describe those elements in terms that are specific and descriptive to one of skill in the art, especially in view of the guidance provided by the specification.

The Examiner's basis for rejection in the final office action is to assert that Alby "clearly replaces a disc nucleus and satisfies such claim terminology." There is nothing in Alby to show that the device actually replaces a disc nucleus, or is a disc prosthesis. As stated by Alby, the "object of the invention is to satisfy this need by proposing an intervertebral link device designed to damp axial compression and traction movements, and also lateral bending movements and bending and stretching movements in the antero-posterior plane." Col. 2, lines 14-19. In other words, Alby links vertebrae to dampen motion and dampen bending movements of the spine, to allow for bone fusion. There is no teaching of a disc, or a disc prosthesis, or a disc nucleus replacement, by these or any other words.

Furthermore, the statement by the Examiner that Alby "clearly replaces" is unsupported by citation to any teaching within Alby that would suggest that the device is placed, or sandwiched between, two adjacent vertebrae. Alby, in fact, teaches that the device is not so situated. Alby accomplishes the linking of vertebrae by connecting the device to implants or bone anchor elements of the pedicular screw type. Col. 2, lines 64-66. Here Alby is showing that the device is connected to the pedicles of a vertebrae, thus Alby *cannot* be a replacement for a disc or a disc nucleus. Alby is connected to parts of the spine that do not allow for connection of a disc replacement between the vertebrae. To reach the pedicles, the device of Alby must extend beyond the intervertebral space. The device of Alby is used to support the natural features in the spinal column. The device is therefore placed out of the spinal column and aligns parallel to the spinal column, but not in-line with the spinal column.

Alby fails to teach a disc prosthesis or disc nucleus replacement. The device of Alby is used on a spine that is in need of immobilization at a position of at least two vertebrae so that those vertebrae may fuse together. In other words, the disc of the spine to be used in Alby is either inoperative, or will be incorporated into the fusion of the adjacent vertebrae. Thus, the person to which the device of Alby is attached, loses motion at that region of the spine during and after the fusion process. Conversely, a person in which the presently claimed system is used retains motion of the vertebrae surrounding the disc prosthesis or disc nucleus replacement.

The Examiner also addresses this motion of the spine issue by stating that "fusion between two vertebrae does not prevent 'mobility of the spine,' since there are many joints in a spine and the fusion of one of such joints cannot be said to prevent mobility of the spine." Office Action, page 5. While Applicant does not disagree with this statement, it is pointed out that it is not the full spine that is to be considered, but rather the joints to which the device is applied and affects. With the device of Alby, the joint between two vertebrae, that once freely moved in relation to one another before application of the device, is rendered devoid of motion after fusion. Conversely, motion in the corresponding joint of a person in which the present system is used is retained. Further, it is noted that fusion at even one vertebral joint will severely restrict a patient's mobility, putting additional stress and strain on the vertebral joints that are adjacent to the site of fusion in a spinal column. In such fusions, this can cause rapid degradation of those other joints (sympathetic degradation), whereas devices that preserve motion are preferred, as they do not cause such sympathetic degradation.

The specifications, being the single best guide to the respective inventions of the Applicant and Alby, clearly describe to one of skill in the art, different inventions, and the claims of the Applicant do not read on Alby's device, as Alby fails to teach each and every element of the claimed invention. As such, Applicant respectfully requests withdrawal of the present rejection.

II. Claim Rejections Under 35 U.S.C. § 103.

Alby and Crozet

Claims 13 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Alby in view of U.S. Patent No. 6,217,578, issued to Crozet *et al.* Applicant respectfully traverses this rejection.

Applicant submits that, as noted above, Alby fails to provide for each and every element of Claim 1, from which claims 13 and 14 depend. Applicant also submits that Alby alone fails to obviate the presently claimed invention, as Alby does not, and cannot, teach or give reason to one of skill in the art to use the device of Alby in connection with a disc prosthesis or disc nucleus replacement. As Applicant described above, and in the previous response, Alby is directed to

spinal fusion of at least one vertebral connection. By teaching such fusion, Alby rather pointedly teaches away from any combination with a disc prosthesis or disc nucleus replacement. Simply put, fusion prevents motion between adjacent vertebrae. The presently claimed invention serves to maintain the freedom of motion of the spine across *all* vertebral connections, while being supported by the claimed device.

Furthermore, Crozet fails to fill the voids of Alby. Crozet is directed to a vertebral osteosynthesis device that can be used to brace a spine ... or to strengthen or brace a deviated spine. Col. 1, lines 5-11. To accomplish this, the device provided is a cross connector device having a low profile that allows for substantial degree of freedom between the hooks of the device. Col. 2, lines 15-18. The cross connector device is for coupling dual rods of an orthopaedic apparatus together to provide enhanced stability thereto. Col. 7, lines 29-32. There simply is no teaching of a device with at least the element of "a disc prosthesis or a disc nucleus replacement."

Because Crozet fails to correct the deficiency of Alby with respect to Claim 1, from which claims 13 and 14 depend, Applicant request that the Examiner withdraw the rejection based upon Alby and Crozet and allow the application to move forward to issuance.

Alby and Karpman

Claim 15 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Alby in view of U.S. Patent No. 6,214,012, issued to Karpman *et al.* Applicant respectfully traverses this rejection.

As noted above, Alby fails to teach each and every element of the claims as pending, and Applicant submits that Karpman fails to fill the void. Karpman is directed to a bone screw which is configured for delivery of an injectable material into a bone. Col. 1, lines 6-9. Applicant submits that while a bone screw is taught for the delivery of a material to a diseased site, there is no teaching or suggestion in Karpman of at least the element of "a disc prosthesis or a disc nucleus replacement." As such, Applicant respectfully requests withdrawal of the noted rejection.

III. Rejoinder

In view of the above remarks, Applicant respectfully requests rejoinder of withdrawn Claim 3. In the Office Action, mailed May 4, 2007, the Examiner had acknowledged that once a generic claim, in this case, Claim 1, was found allowable, non-elected species would be subject to rejoinder. Page 3. In the same Office Action, the Examiner alleged that because there is no art of record that a plate and a rod are obvious variants, they are distinct species. Page 2. However, in view the primary Alby reference cited by the Examiner in this and the previous Office Actions, this is no longer a true statement, as the interchangeability of plates and rods is now of record. At Col. 1, lines 50-55, Alby states;

> Nevertheless, it appears that an intervertebral stabilization device, *whether of the plate type or of the rod type*, once implemented, constitutes a system that is rigid, thereby applying mechanical stresses to the intervertebral joints adjacent to the joint being stabilized.

Thus, there is evidence in the art, cited to by the Examiner, that one of skill in the art would consider a rod and a plate to be interchangeable species in spinal devices.

As Claim 1 distinguishes over the cited art for the reasons presented above, Applicant respectfully submits that Claim 3 may be rejoined with the other pending claims, as dependent upon an allowable generic claim.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is earnestly solicited. The Examiner is requested to contact the undersigned by telephone if a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date June 2, 2008

By _____

Jeffrey R. Lomprey
Attorney for Applicant
Registration No. 55,401

FOLEY & LARDNER LLP
Customer Number: 23524
Telephone: (608) 258-4288
Facsimile: (608) 258-4258